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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/681,560 | 10/08/2003 | William M. Hung | 60126.0003US01 | 9449 |
| 23552 | 7590 | 06/06/2005 | EXAMINER | |
| MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903 | | | WHITE, EVERETT NMN | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1623 | |

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/681,560

Applicant(s)

HUNG ET AL.

Examiner

EVERETT WHITE

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 45-50 is/are allowed.
- 6) ☒ Claim(s) 1-20, 27-40 and 44 is/are rejected.
- 7) ☒ Claim(s) 21-26 and 41-43 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 02/05/2004.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: ____.

AS

DETAILED ACTION

Claim Rejections - 35 USC § 112

1. The following is a quotation of the second paragraph of 35 U.S.C. 112:
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.
2. Claims 1-20, 27-40 and 44 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "low" in the phrase "low endotoxin content" in Claims 1, 27 and 44 is a relative term, which renders the claim indefinite. The term "low endotoxin content" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Claims 2-20 and 28-40, which are dependent from Claims 1 and 27, are also rejected since these claims do not clarify "low endotoxin content".

In Claim 11, the term "tetrabutylammonium bromide" lacks clear antecedent basis since Claim 11 is dependent from Claim 10. This term has not been established in Claim 11. The phrase "phase transfer agent comprises" should be changed to - - quaternary ammonium salt is - - in order to overcome this rejection.

In Claim 12, line 2, the term "salts" should be changed to - - salt - -.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claim 44 is rejected under 35 U.S.C. 102(b) as being anticipated by Tanzawa et al (JP362184002A).

Applicants claim a water-soluble chitosan having low endotoxin content form by the method of Claim 27. Instant Claim 44 is in the form of a product-by-process. The Office considers a product-by-process claim to be product claim. Applicants are reminded that process limitations cannot impart patentability to a product that is not patentably distinguished over the prior art. *In re Thorpe et al.* (CAFC 1985), supra; *In re Dike* (CCPA 1968) 394 F2d 584, 157 USPQ 581; *Tri-Wall Containers, Inc. v. United States et al.* (Ct Cls 1969) 408 F2d 748, 161 USPQ 116; *In re Brown et al.* (CCPA 1972) 450 F2d 531, 173 USPQ 685; *Ex parte Edwards et al.* (BPAI 1986) 231 USPQ 981. Instant Claim 44 is also limited by the phrase "low endotoxin content" which is too vague. The metes and bounds of this term cannot be determined (see 112 rejection above). Hence, the claim reads on any water-soluble chitosan.

The Tanzawa et al patent discloses low-MW water-soluble chitosan, which anticipate the water-soluble chitosan of instant Claim 44.

Allowable Subject Matter

5. Claims 45-50 are allowed.
6. Claims 21-26 and 41-43 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.
7. Claims 1 and 27 would be allowable if rewritten or amended to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action.
8. Claims 2-20 and 28-40 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Statement Of Reason For Allowance

9. The following is a statement of reasons for the indication of allowable subject matter: US Patent No. 4,885,168 to Hashimoto et al and US Patent No. 5,169,535 to Adachi et al appears to be representative of the closest prior art of record. The Hashimoto et al patent discloses a method for the removal of nucleic acids and endotoxin from a liquid containing same and proteins which comprises adding sufficient amount of a low molecular weight chitosan into the liquid to precipitate the nucleic acids and endotoxin present in the liquid and separating off said precipitate, thereby retaining a substantial portion of the proteins in said liquid. The Adachi et al patent discloses a method of removing endotoxin from a solution containing only endotoxin as an absorbed material, wherein the pH value of the solution is adjusted to pH 9 or lower and subsequently, the solution is passed through a column packed with crosslinked granular chitosan. However, neither patents discloses water-soluble chitosan having low endotoxin content or a method of making water-soluble chitosan that involved adjusting the pH of an aqueous solution to cause precipitation of water-soluble chitosan having low endotoxin content. U.S. Publication No. 2002/0018732 was also noted. See Claim 18 of this publication which recites a process for producing a water soluble O-acetylated chitosan or chitosan derivative, comprising the steps of dissolving a chitosan or chitosan derivative in an aqueous acidic solution and reacting the chitosan or chitosan derivative with an acetylating agent in the presence of a phase transfer reagent. The process of the instant claims differ from the publication by reciting an initial step that involves contacting a water-insoluble chitosan in a basic solution as opposed to an aqueous acidic solution.

Information Disclosure Statement

10. The information disclosure statement filed February 5, 2004 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

11. The information disclosure statement filed February 5, 2004 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Summary

12. Claims 45-50 are allowed; Claims 1-20, 27-40 and 44 are rejected; Claims 21-26 and 41-43 are objected to.

Examiner's Telephone Number, Fax Number, and Other Information

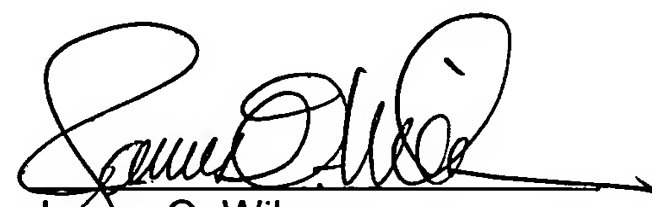
13. For 24 hour access to patent application information 7 days per week, or for filing applications, please visit our website at www.uspto.gov and click on the button "Patent Electronic Business Center" for more information.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Everett White whose telephone number is (571) 272-0660. The examiner can normally be reached on Monday-Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, can be reached on (571) 272-0661. The fax phone number for this Group is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-1235.


E.White


James O. Wilson
Supervisory Primary Examiner
Technology Center 1600